

MAR 29 2001

510(k) SUMMARY

K004039

Submitter:

Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, MA 01824

Contact:

George Cho
Senior Vice President of Medical Technology

Date Summary Prepared:

December 28, 2000

Device Trade Name:

PhotoGenica neo-v

Common Name:

Medical Laser System

Classification Name:

Instrument, surgical, powered, laser
79-GEX
21 CFR 878.48

Equivalent Device:

Cynosure PhotoGenica V

Device Description:

The PhotoGenica neo-v is a pulse-dye laser, having the organic dye as the lasing medium. It is a pulsed laser with a wavelength of 585nm.

Laser activation is both by finger switch and footswitch. Overall weight of the laser is 285lbs, and the size is 44"x19"x24" (HxWxD).

Electrical requirement is 110 VAC or 220 VAC, 20A, 50-60 Hz, single phase.

Intended Use:

The PhotoGenica neo-v is indicated for benign vascular and vascular dependent lesions such as warts, scars, and psoriasis.

Comparison:

The PhotoGenica neo-v laser has an equivalent indication for uses, the same principle of operation, the same wavelength and pulse energy range as the predicate devices.

Nonclinical Performance Data:

none

Clinical Performance Data:

none

Conclusion:

The PhotoGenica neo-v Laser is another safe and effective device for dermatologic applications.

Additional Information:

none



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 29 2001

Mr. George Cho
Senior Vice President of
Medical Technology
Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, Massachusetts 01824

Re: K004039
Trade Name: Cynosure PhotoGenica neo-v
Regulatory Class: II
Product Code: GEX
Dated: December 28, 2000
Received: December 29, 2000

Dear Mr. Cho:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

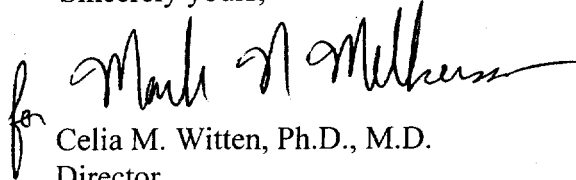
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. George Cho

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.

Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

501(k) Number (if known): K004039

Device Name: Cynosure PhotoGenica neo-v

Indications For Use:

The Cynosure PhotoGenica neo-v laser is indicated for the treatment of benign cutaneous vascular or vascular dependent lesions, such as warts, scars, and psoriasis.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Miller

(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K 004039

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format I-2-96)